

Attorney's Docket No.01841-578

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Patent NOV 26 2001

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In re Patent Application of)
Ricci, et al.) Group Art Unit: Unassigned
Application No.: 09/954,789) Examiner: Unassigned
Filed: September 12, 2001)
For: METHODS FOR TREATING)
ENDOLEAKS DURING)
ENDOVASCULAR REPAIR OF)
ABDOMINAL AORTIC ANEURYSMS)

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents was submitted in Application No. 09/528,656 upon which is based a claim for priority under 35 U.S.C. § 120.

The documents are being submitted before the first Office Action on the merits, whichever is later, therefore no fee or certification is required under 37 C.F.R. § 1.97(b).

U.S. Patents:

1. U.S. Patent No. 3,527,224, issued September 8, 1970, to Rabinowitz.
2. U.S. Patent No. 3,591,676, issued July 6, 1971, to Hawkins, et al.
3. U.S. Patent No. 4,795,741, issued January 3, 1989, to Leschiner, et al.
4. U.S. Patent No. 4,938,763, issued July 3, 1990, to Dunn, et al.
5. U.S. Patent No. 5,580,568, issued December 3, 1996, to Greff, et al.
6. U.S. Patent No. 5,667,767, issued September 16, 1997, to Greff, et al.
7. U.S. Patent No. 5,695,480, issued December 9, 1997, to Evans, et al.
8. U.S. Patent No. 5,702,361, issued December 30, 1997, to Evans, et al.

9. U.S. Patent No. 5,749,894, issued May 12, 1998, to Engelson.
10. U.S. Patent No. 5,749,922, issued May 12, 1998, to Slepian, et al.
11. U.S. Patent No. 5,868,778, issued February 9, 1999, to Gershony, et al.

Foreign Patents:

12. Japanese Patent No. 406,107,549, issued April 19, 1994, to Mandai, et al., with English Language Abstract.

The Applicants also note the following copending application which is related to this application, a copy of which is not enclosed.

Patent Application:

13. U.S. Patent Application Serial No. 08/802,252, filed February 19, 1997, Evans, et al.

Other Documents:

14. Beebe, et al., "Current Status of the United States Vanguard™ Endograft Trial", *JPVA* 2.1-2.3, Presented at the 6th Annual Symposium on Current Issues and New Techniques in Interventional Radiology at New York, New York in November, 1998.
15. Castaneda-Zuniga, et al., "Interventional Radiology", *Vascular Embolotherapy*, Part I, 1:9-32, Williams & Wilkins, (1992).
16. Hopkinson, et al., "Current Critical Problems, New Horizons and Techniques in Vascular and Endovascular Surgery", *JPIII* 4.1-4.2, Presented at the 6th Annual Symposium on Current Issues and New Techniques in Interventional Radiology at New York, New York in November, 1998.
17. Karch, et al., "Algorithm for the Diagnosis and Treatment of Endoleaks", *Am. J. Surg.*, 178:225-231 (1999).
18. Kinugasa, et al., "Direct Thrombosis of Aneurysms with Cellulose Polymer", *J. Neurosurg.*, 77:501-507 (1992).
19. Kinugasa, et al., "Early Treatment of Subarachnoid Hemorrhage After Preventing Rerupture of an Aneurysm", *J. Neurosurg.*, 83:34-41 (1995).
20. Kinugasa, et al., "Prophylactic Thrombosis to Prevent New Bleeding and to Delay Aneurysm Surgery", *Neurosurg.*, 36:661 (1995).

21. Marty, et al., "Endoleak After Endovascular Graft Repair of Experimental Aortic Aneurysms: Does Coil Embolization with Angiographic "Seal" Lower Intraaneurysmal Pressure", *J. Vasc. Surg.*, 27:(2):213-221 (1998).
22. May, et al., "Concurrent Comparison of Endoluminal Versus Open Repair in the Treatment of Abdominal Aortic Aneurysms: Analysis of 303 Patients by Life Table Method", *J. Vasc. Surg.*, 27:213-221 (1998).
23. Miahle, et al., "Endovascular Treatment of Infrarenal Abdominal Aortic Aneurysms by the Stentor System: Preliminary Results of 79 Cases", *J. Vasc. Surg.*, 26:199-209 (1997).
24. Money, et al., "Perioperative Charge Comparison and Endovascular Abdominal Aortic Aneurysm Repair", *JPV* 1.1-1.2, Presented at the 6th Annual Symposium on Current Issues and New Techniques in Interventional Radiology at New York, New York, in November, 1998.
25. Parodi, "Endovascular AAA Stent Grafts: Technology, Training and Proper Patient Selection", *JPV*, 1.1-1.2, Presented at the 6th Annual Symposium on Current Issues and New Techniques in Interventional Radiology at New York, New York in November, 1998.
26. Taki, et al., "Selection and Combination of Various Endovascular Techniques in the Treatment of Giant Aneurysms", *J. Neurosurg.*, 77:37-42 (1992).
27. Van Schie, et al., "Successful Embolization of Persistent Endoleak from a Patient Inferior Mesenteric Artery", *J. Endovasc. Surg.*, 4:312-315 (1997).
28. Wain, et al., "Endoleaks after Endovascular Graft Treatment of Aortic Aneurysms: Classification, Risk Factors, and Outcome", *J. Vasc. Surg.*, 27:69-80 (1998).
29. Walker, et al., "A Study on the Patency of the Inferior Mesenteric and Lumbar Arteries in the Incidence of Endoleak Following Endovascular Repair of Infra-renal Aortic Aneurysms", *Clinical Radiology*, 53:593-595 (1997).
30. White, et al., "Endoleaks - A Proposed New Terminology to Describe Incomplete Aneurysm Exclusion by an Endoluminal Graft", *J. Endovasc. Surg.*, 3:124-125 (1996).
31. White, et al., "Endoleak as a Complication of Endoluminal Grafting of Abdominal Aortic Aneurysms: Classification Incidence, Diagnosis, and Management", *J. Endovasc. Surg.*, 4:152-158 (1997).
32. Registry CopyRight 2000 ACS 6606-65-1 Registry files (5/2000).
33. Registry CopyRight 2000 ACS 25154-80-7 Registry files (5/2000).
34. Registry CopyRight 2000 ACS 87435-86-7 Registry Files (5/2000).

35. Registry CopyRight 2000 ACS 79817-44-0 Registry files (5/2000).
36. Registry CopyRight 2000 ACS 12619-85-1 Registry files (5/2000).
37. Schurink, et al., "Endoleak after Stent-graft Treatment of Abdominal Aortic Aneurysm: A Meta-analysis of Clinical Studies", *British Journal of Surgery*, 86:581-587, (1999).
38. Holzenbein, et al., "Endovascular Management of "Endoleaks" after Transluminal Infrarenal Abdominal Aneurysm Repair", *Eur. J. Vasc. Endovasc. Surg.*, 16:208-217, September (1998).
39. Makaroun, et al., "Fate of Endoleaks after Endoluminal Repair of Abdominal Aortic Aneurysms with the EVT Devise", *Eur. J. Vasc. Endovasc. Surg.*, 18:185-190, September (1999).
40. Walker, et al., "Endovascular AAA Repair: Prevention of Slide Branch Endovascular Endoleaks with Thrombogenic Sponge", *J. Endovasc. Surg.*, 6:350-353, November (1999).
41. Buth, et al., "Early Complications and Endoleaks after Endovascular Abdominal Aortic Aneurysm Repair: Report of a Multicenter Study", *J. Vasc. Surg.*, 31 (1):134-146, January (2000).
42. Jacobowitz, et al., "The Significance and Management of the Leaking Endograft", *Seminars in Vascular Surg.*, 12(3):199-206, September (1999).
43. Amseur, et al., "Embolotherapy of Persistent Endoleaks after Endovascular Repair of Abdominal Aortic Aneurysm with the Ancure-Endovascular Technologies Endograft System", *JVIR* 10:1175-1182, October (1999).
44. Broeders, et al., "The role of infrarenal aortic side branches in the pathogenesis of endoleaks after endovascular aneurysm repair" *Eur. J. Vasc. Endovasc. Surg.* 16:419-426 (1998).

Copies of the listed documents were previously submitted in prior Application Serial No. 09/528,656, filed March 20, 2000, upon which rely for the benefits provided in 35 U.S.C. § 120. In accordance with 37 C.F.R. § 1.98(d), copies of the listed documents are not included.

While this Information Disclosure Statement may contain material information pursuant to 37 C.F.R. § 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to herein is "prior art" to the invention disclosed and claimed in the above-referenced application unless specifically designated as such.

Information Disclosure Statement
Application No. 09/954,789
Attorney's Docket No. 018413-378
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Applicants specifically reserve the right, where appropriate, to antedate any such reference by the appropriate showing under 37 C.F.R. § 1.131 and § 1.608, or any other appropriate means.

The documents are being submitted within three months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later, therefore no fee or certification is required under 37 C.F.R. § 1.97(b).

In the event that an Office Action on the merits has been mailed before the filing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge required fees to our Deposit Account No. 02-4800.

This Information Disclosure Statement is not a representation that a search has been made or that no other information material to the patentability of this invention exists.

To assist the Examiner, the listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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Date: November 20, 2001



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**INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTER**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

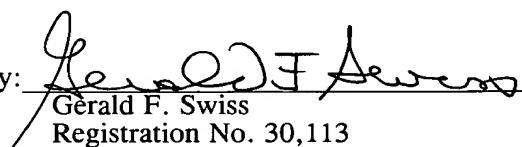
Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- No additional fee for submission of an IDS is required.
- The fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- A certification under 37 C.F.R. § 1.97(e) is also enclosed.
- A certification under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- Charge \$_____ to Deposit Account No. 02-4800 for the fee due.
- A check in the amount of \$_____ is enclosed for the fee due.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

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Date: November 20, 2001